

Application No.: 10/524,395

Docket No.: ALXN-P01-093

REMARKS

Claims 1-8, 10-12, and 16 were pending and under examination. By virtue of this amendment, claims 3-4 have been canceled, without prejudice. Claims 1, 5-7, and 10-12 have been amended and claims 33-38 have been added. The claim amendments and additions add no new matter. Support for the subject matter of the newly added claims and claim amendments is found throughout the specification and previously pending claims. In particular, support for the amendment to claim 1 may be found, for example, in claims 3 and 4 as originally pending. The amendments to claims 5-7 and 11 were made to maintain proper antecedent basis in view of the amendments to claim 1. Support for the amendment to claim 10 may be found, for example, in paragraph [0047] of the published application (US Publication No. 2006/0233805). Support for the amendment to claim 12 may be found, for example, in the claims as originally filed, Example 8, and Figures 8A-F. Support for claims 33-38 may be found in claims 2, 5-8 and 10, respectively. In addition, support for claim 33 may be found in paragraph [0034]. Support for claims 34-36 may be found, for example, in Figure 8A-F. Support for claim 37 may be found, for example, in paragraph [0024]. Support for claim 38 may be found, for example, in paragraph [0047].

Amendment or cancellation of claims should in no way be construed as an acquiescence to any of the rejections. The amendments to the claims are being made solely to expedite prosecution of the present application. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office Action will be addressed below in the order they appear in the Office Action.

Double patenting

Claims 1-8, 10-12, and 16 have been provisionally rejected on the grounds of non-statutory double patenting as being unpatentable over copending Application Nos. 10/524,394, 10/625,202, and 11/904,045, and US Patent No. 7,285,642. The grounds for the double patenting rejections are the same in each instance. The Examiner asserts the cited applications

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and patent all have claims that involve administering antibodies AZN-D1 and AZN-D2. The Examiner further alleges that the claims of the instant application would have read on any degree of exposure to a given microorganism and that everyone, including those in the claims of the cited applications and patent, would have been exposed to *Candida* and *Aspergillus*. As such, the Examiner alleges that the claims of the instant application and the cited applications and patent were not patentably distinct.

Applicants respectfully disagree with the rejection. However, in an effort to expedite prosecution of the instant application, the claims have been amended and the amendments are believed to obviate the rejection. In particular, claim 1 has been amended to specify that an anti-DC-SIGN antibody is administered to treat a subject suffering from an infection with a yeast or fungus and Claim 12 has been amended to specify that the method involves inhibiting an infection by a yeast or fungus in a subject. Both methods involve administering an anti-DC-SIGN antibody to a subject *in need of* such treatment. The Examiner stated that *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans. However, someone who has *Candida* or *Aspergillus* as part of his natural flora does not represent someone who *is need of* treatment or inhibition of a *Candida* or *Aspergillus* infection. Furthermore, Applicants in the instant application were the first to demonstrate that the DC-SIGN receptor on dendritic cells binds to yeast and fungi. Accordingly, it could not have been known before the instant application that someone in need of treatment or inhibition of a yeast or fungal infection was someone *in need of* treatment with an anti-DC-SIGN antibody.

The patients in the cited applications and patent receive treatment with antibodies that bind to DC-SIGN for other reasons, not because of a need for treating or inhibiting a yeast or fungal infection. Therefore, the population of subjects being treated in the instant application is distinct from the subjects being treated in the cited applications and patents. *See, e.g., Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (stating that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose [because] it is a statement of the intentional purpose for which the method must be performed"); *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001). Accordingly, Applicants submit that claims of the instant application are not anticipated by or obvious in view of the claims in the

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cited applications or patent. Reconsideration and withdrawal of the double patenting rejections is respectfully requested.

35 U.S.C § 112, first paragraph

Claim 10 was rejected under 35 U.S.C § 112, first paragraph, for lack of enablement. As requested by the Examiner, the claims have been amended to refer to antibodies produced by deposited hybridoma cell lines having (e.g., ECACC accession numbers 99040818, 99040819, and 03071801).

These deposits were made under the terms of the Budapest Treaty. A copy of the ECACC deposit receipts are attached hereto as Exhibits A, B and C. The undersigned attorney of record hereby states that in accordance with 37 CFR §1.808(a)(2), and except as permitted by 37 CFR §1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on the above-referenced application.

The amendments and statements made herein are believed to obviate the rejection. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

35 U.S.C § 112, second paragraph

Claim 10 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for recitation of AZN-D1, AZN-D2 and AZN-D3. As requested by the Examiner, claim 10 has been amended to refer to antibodies produced by hybridomas referenced by their ECACC deposit accession number. The amendment is believed to obviate the rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 102

Claims 1-8, 10-12 and 16 were rejected under 35 U.S.C § 102(b) as allegedly being anticipated by Figdor et al. (WO 00/63251). Claims 1-8, 10-12, and 16 are also rejected under

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35 U.S.C § 102(e) as being anticipated by Olson et al. (US Patent Application Publication 2003/0134297). Finally, Claims 1-8, 10-12 and 16 are rejected under 35 U.S.C § 102(e) as being anticipated by Figdor et al. (US Patent 7,285,642). The Examiner asserts that each of the cited references anticipates the pending claims because the cited references disclose the use of the antibodies AZN-D1 and AZN-D2 for treating or preventing HIV infection (Figdor et al.), treatment of HCV infection (Olson et al.), or increasing an immune response in a subject (Figdor et al.). The Examiner further alleged that the claims of the instant application would have encompassed the subjects in the cited references, because everyone has been exposed to *Candida* and *Aspergillus*.

Applicants respectfully disagree with the rejection. However, in an effort to expedite prosecution of the instant application, the claims have been amended and the amendments are believed to obviate the rejection. In particular, claim 1 has been amended to specify that an anti-DC-SIGN antibody is administered to treat a subject suffering from an infection with a yeast or fungus and Claim 12 has been amended to specify that the method involves inhibiting an infection by a yeast or fungus in a subject. Both methods involve administering an anti-DC-SIGN antibody to a subject *in need of* such treatment. The Examiner stated that *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans. However, someone who has *Candida* or *Aspergillus* as part of his natural flora does not represent someone who *is need of* treatment or inhibition of a *Candida* or *Aspergillus* infection. Furthermore, Applicants in the instant application were the first to demonstrate that the DC-SIGN receptor on dendritic cells binds to yeast and fungi. Accordingly, it could not have been known before the instant application that someone in need of treatment or inhibition of a yeast or fungal infection was someone *in need of* treatment with an anti-DC-SIGN antibody.

The patients in the cited references receive treatment with antibodies that bind to DC-SIGN for other reasons, not because of a need for treating or inhibiting a yeast or fungal infection. Therefore, the population of subjects being treated in the instant application is distinct from the subjects being treated in the cited references. See, e.g., *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (stating that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose [because] it is a statement of the intentional purpose for which the method must be performed"); *Rapoport v. Dement*, 254

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F.3d 1053 (Fed. Cir. 2001). Accordingly, Applicants submit that claims of the instant application are not anticipated by or obvious in view of the cited references. Reconsideration and withdrawal of the rejections under 35 U.S.C. 102(b) and (e) is respectfully requested.

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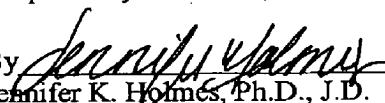
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CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to Deposit Account No. 18-1945, under Order No. ALXN-P01-093.

Dated: October 17, 2008

Respectfully submitted,

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